

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 1 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE FIGURES

In sheet 1 and the Title page, in FIGURE 1, please delete "conc ntration" on the y-axis of the graph and replace with --concentration-- as shown in attached sheets.

(12) **United States Patent**
Ryde et al.

(10) Patent No.: **US 7,320,802 B2**
 (45) Date of Patent: **Jan. 22, 2008**

(54) **METHODS OF TREATMENT USING
 NANOPARTICULATE FENOFIBRATE
 COMPOSITIONS**

(75) Inventors: Tuula Ryde, Malvern, PA (US); Evan E. Gustow, Villanova, PA (US); Stephen B. Ruddy, Schwenksville, PA (US); Rajeev Jain, Collegeville, PA (US); Rakesh Patel, Bensalem, PA (US); Michael John Wilkins, Middleton (IE)

(73) Assignees: Elan Pharma International, Ltd., Athlone, County Westmath (IE); Fournier Laboratories Ireland Ltd., Cork (IE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 233 days.

(21) Appl. No.: 10/692,855

(22) Filed: Oct. 27, 2003

(65) Prior Publication Data
 US 2004/0058009 A1 Mar. 25, 2004

Related U.S. Application Data

(60) Division of application No. 10/444,066, filed on May 23, 2003, now Pat. No. 7,276,249, which is a continuation-in-part of application No. 10/370,277, filed on Feb. 21, 2003, now abandoned.

(60) Provisional application No. 60/383,294, filed on May 24, 2002.

(51) Int. Cl.
 A61K 9/20 (2006.01)
 A61K 9/48 (2006.01)
 A61K 9/14 (2006.01)
 A06K 9/14 (2006.01)

(52) U.S. Cl. 424/451; 424/458; 424/464;
 424/469; 424/470; 424/489; 424/490

(58) Field of Classification Search 424/400, 424/489, 451, 458, 464, 469, 470, 490
 See application file for complete search history.

(56) References Cited
 U.S. PATENT DOCUMENTS
 3,907,792 A 9/1975 Micville
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The Physicians' Desk Reference, 56th Ed., pp. 513-516 (2002).

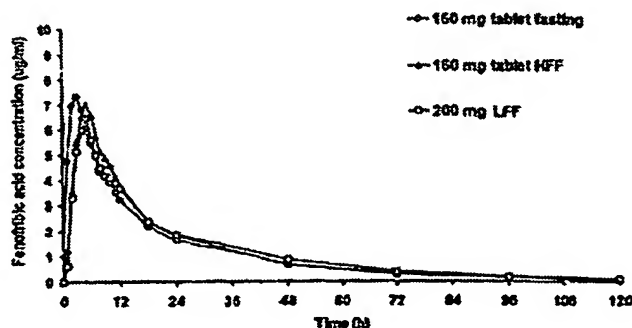
(Continued)

Primary Examiner—Shelley A. Dodson
 Assistant Examiner—Konata M. George
 (74) Attorney, Agent, or Firm—Foley & Lardner LLP

(57) **ABSTRACT**

The present invention is directed to fibrate compositions having improved pharmacokinetic profiles and reduced fed/fasted variability. The fibrate particles of the composition have an effective average particle size of less than about 2000 nm.

396 Claims, 2 Drawing Sheets

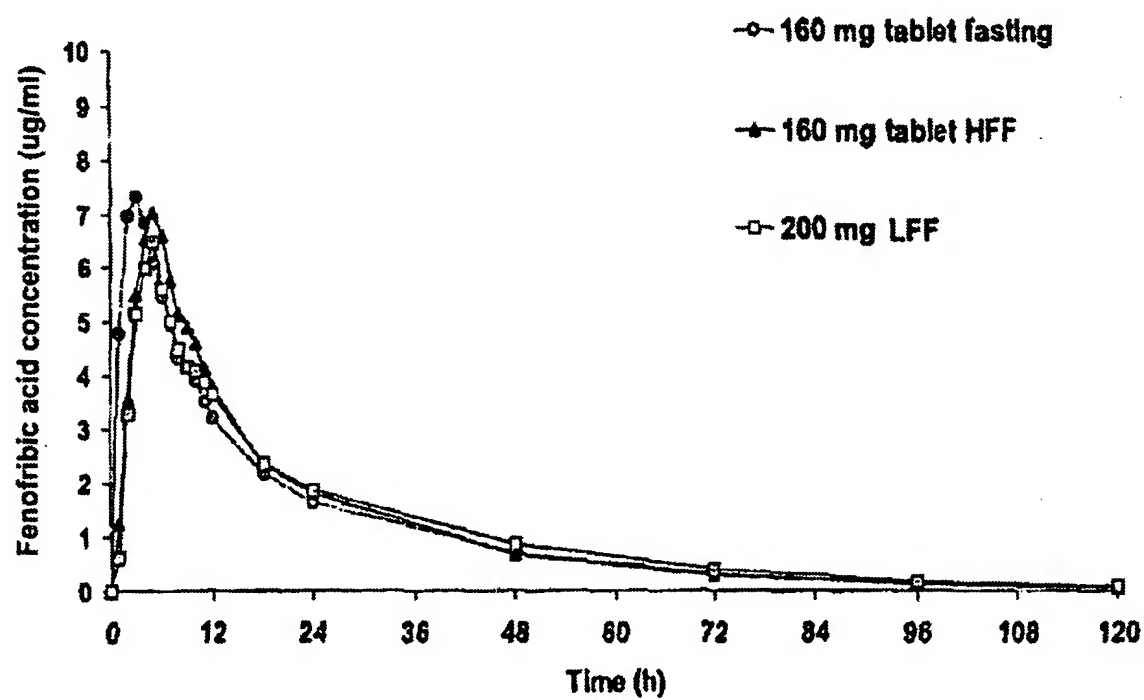


U.S. Patent

Jan. 22, 2008

Sheet 1 of 2

7,320,802 B2

FIGURE 1

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 4 of 18

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IN THE SPECIFICATION

In column 6, line 15, please delete the term “know” and replace with --known--.

In column 9, lines 16-17, please delete the phrase “Physicians Desk Reference” and replace with *Physicians' Desk Reference*--.

In column 9, line 42, please delete the term “ug/mL.h” and replace with --ug/ml.h--.

In column 14, line 10, please delete “Searle=s” and replace with --Searle's--.

In column 16, lines 21-22, please delete the term “n-noyl β -D-glucopyranoside” and replace with --n-nonyl β -D-glucopyranoside--.

In column 29, line 3, please delete “Analyzer ((Horiba” and replace with --Analyzer (Horiba--.

IN THE CLAIMS

In claim 8, column 35, line 62, please delete the term “ μ g/mL.h” and replace with -- μ g/mL.h--.

In claim 11, column 36, line 19, please delete the term “g/kg” and replace with the term --g--.

In claim 11, column 36, line 22, please delete the term “g/kg” and replace with the term --g--.

In claim 11, column 36, line 25, please delete the term “g/kg” and replace with the term --g--.

In claim 11, column 36, line 28, please delete the term “g/kg” and replace with the term --g--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
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DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 5 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 14, column 36, line 59, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 15, column 36, line 65, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 16, column 37, line 4, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 17, column 37, line 10, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 18, column 37, line 17, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 18, column 37, line 18, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 18, column 37, line 19, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 18, column 37, line 20, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 19, column 37, line 27, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 20, column 37, line 33, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 21, column 37, line 36, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 22, column 37, line 43, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
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Page 6 of 18

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In claim 23, column 37, line 49, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 24, column 37, line 57, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 24, column 37, line 58, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 24, column 37, line 59, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 24, column 37, line 60, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 24, column 37, line 61, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 53, column 40, line 31, please delete "n-noyl" and replace with --n-nonyl--.

In claim 53, column 40, lines 65-66, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

In claim 53, column 40, line 67, through column 41, line 1, please delete the term "N-tetradecyldimethylbenzyl ammonium, chloride monohydrate" and replace with --tetradecyldimethylbenzyl ammonium chloride monohydrate--.

In claim 62, column 42, line 8, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 65, column 42, line 32, please delete the term "g/kg" and replace with the term --g--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
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DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 7 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 65, column 42, line 35, please delete the term "g/kg" and replace with the term --g--.

In claim 65, column 42, line 38, please delete the term "g/kg" and replace with the term --g--.

In claim 65, column 42, line 41, please delete the term "g/kg" and replace with the term --g--.

In claim 68, column 43, line 6, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 69, column 43, line 12, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 70, column 43, line 18, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 71, column 43, line 24, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 72, column 43, line 31, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 72, column 43, line 32, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 72, column 43, line 33, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 72, column 43, line 34, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 73, column 43, line 41, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 8 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 74, column 43, line 47, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 75, column 43, line 50, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 76, column 43, line 57, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 77, column 43, line 63, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 78, column 44, line 3, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 78, column 44, line 4, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 78, column 44, line 5, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 78, column 44, line 6, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 78, column 44, line 7, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 107, column 46, line 44, please delete "n-noyl" and replace with --n-nonyl--.

In claim 107, column 47, lines 11-12, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 9 of 18

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In claim 107, column 47, lines 14-15, please delete the term
N-tetradecyldimethylbenzyl ammonium, chloride monohydrate” and replace with
--tetradecyldimethylbenzyl ammonium chloride monohydrate--.

In claim 116, column 48, line 22, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 119, column 48, line 47, please delete the term “g/kg” and replace with
the term --g--.

In claim 119, column 48, line 50, please delete the term “g/kg” and replace with
the term --g--.

In claim 119, column 48, line 53, please delete the term “g/kg” and replace with
the term --g--.

In claim 119, column 48, line 56, please delete the term “g/kg” and replace with
the term --g--.

In claim 122, column 49, line 20, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 123, column 49, line 26, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 124, column 49, line 32, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 125, column 49, line 38, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 126, column 49, line 45, please delete the term “mg/mL” and replace
with the term --µg/mL--.

In claim 126, column 49, line 46, please delete the term “mg/mL” and replace
with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
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Page 10 of 18

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In claim 126, column 49, line 47, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 126, column 49, line 48, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 127, column 49, line 54, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 128, column 49, line 61, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 129, column 49, line 64, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 130, column 50, line 4, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 131, column 50, line 10, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 132, column 50, line 17, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 132, column 50, line 18, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 132, column 50, line 19, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 132, column 50, line 20, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 132, column 50, line 21, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 11 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 161, column 52, line 56, please delete "n-noyl" and replace with --n-nonyl--.

In claim 161, column 53, lines 23-24, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

In claim 161, column 53, lines 26-27, please delete the term "N-tetradecyldimethylbenzyl ammonium, chloride monohydrate" and replace with --tetradecyldimethylbenzyl ammonium chloride monohydrate--.

In claim 170, column 54, line 32, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 173, column 54, line 56, please delete the term "g/kg" and replace with the term --g--.

In claim 173, column 54, line 59, please delete the term "g/kg" and replace with the term --g--.

In claim 173, column 54, line 62, please delete the term "g/kg" and replace with the term --g--.

In claim 173, column 54, line 65, please delete the term "g/kg" and replace with the term --g--.

In claim 176, column 55, line 29, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 177, column 55, line 35, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 178, column 55, line 41, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
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DATED : January 22, 2008
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Page 12 of 18

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In claim 179, column 55, line 47, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 180, column 55, line 54, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 180, column 55, line 55, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 180, column 55, line 56, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 180, column 55, line 57, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 181, column 55, line 64, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 182, column 56, line 3, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 183, column 56, line 6, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 184, column 56, line 13, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 185, column 56, line 19, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 186, column 56, line 26, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 186, column 56, line 27, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

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DATED : January 22, 2008
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Page 13 of 18

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In claim 186, column 56, line 28, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 186, column 56, line 29, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 186, column 56, line 30, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 215, column 58, line 63, please delete "n-noyl" and replace with --n-nonyl--.

In claim 215, column 59, lines 30-31, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

In claim 215, column 59, lines 33-34, please delete the term "N-tetradecyldimethylbenzyl ammonium, chloride monohydrate" and replace with --tetradecyldimethylbenzyl ammonium chloride monohydrate--.

In claim 224, column 60, line 41, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 227, column 60, line 65, please delete the term "g/kg" and replace with the term --g--.

In claim 227, column 61, line 1, please delete the term "g/kg" and replace with the term --g--.

In claim 227, column 61, line 4, please delete the term "g/kg" and replace with the term --g--.

In claim 227, column 61, line 7, please delete the term "g/kg" and replace with the term --g--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 14 of 18

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In claim 230, column 61, line 38, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 231, column 61, line 45, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 232, column 61, line 50, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 233, column 61, line 56, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 234, column 61, line 64, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 234, column 61, line 65, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 234, column 61, line 66, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 234, column 61, line 67, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 235, column 62, line 7, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 236, column 62, line 13, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 237, column 62, line 16, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 238, column 62, line 23, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 15 of 18

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In claim 239, column 62, line 29, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 240, column 62, line 36, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 240, column 62, line 37, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 240, column 62, line 38, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 240, column 62, line 39, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 240, column 62, line 40, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 269, column 65, line 6, please delete "n-noyl" and replace with --n-nonyl--.

In claim 269, column 65, lines 40-41, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

In claim 269, column 65, lines 43-44, please delete the term "N-tetradecyldimethylbenzyl ammonium, chloride monohydrate" and replace with --tetradecyldimethylbenzyl ammonium chloride monohydrate--.

In claim 274, column 66, line 35, please delete "The method of claim 271" and replace with --The method of claim 273--.

In claim 278, column 66, line 50, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 16 of 18

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In claim 281, column 67, line 7, please delete the term "g/kg" and replace with the term --g--.

In claim 281, column 67, line 10, please delete the term "g/kg" and replace with the term --g--.

In claim 281, column 67, line 13, please delete the term "g/kg" and replace with the term --g--.

In claim 281, column 67, line 16, please delete the term "g/kg" and replace with the term --g--.

In claim 284, column 67, line 47, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 285, column 67, line 53, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 286, column 67, line 59, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 287, column 67, line 65, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 288, column 68, line 5, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 288, column 68, line 6, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 288, column 68, line 7, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 288, column 68, line 8, please delete the term "mg/mL" and replace with the term --µg/mL--.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,320,802 B2
APPLICATION NO. : 10/692855
DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

Page 17 of 18

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In claim 289, column 68, line 16, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 290, column 68, line 22, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 291, column 68, line 25, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 292, column 68, line 32, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 293, column 68, line 38, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 294, column 68, line 45, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 294, column 68, line 46, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 294, column 68, line 47, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 294, column 68, line 48, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 294, column 68, line 49, please delete the term "mg/mL" and replace with the term --µg/mL--.

In claim 323, column 71, line 22, please delete "n-noyl" and replace with --n-nonyl--.

In claim 323, column 71, lines 56-57, please delete the term "alkyamidoalkyldialkylammonium salt" and replace with --alkylamidoalkyldialkylammonium salt--.

UNITED STATES PATENT AND TRADEMARK OFFICE
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DATED : January 22, 2008
INVENTOR(S) : Tuula Ryde et al.

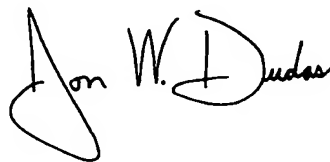
Page 18 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 323, column 71, lines 59-60, please delete the term
“N-tetradecyldimethylbenzyl ammonium, chloride monohydrate” and replace with
--tetradecyldimethylbenzyl ammonium chloride monohydrate--.

Signed and Sealed this

Fifteenth Day of July, 2008

A handwritten signature in black ink, appearing to read "Jon W. Dudas". The signature is stylized with a large, looped initial "J" and a cursive "Dudas".

JON W. DUDAS
Director of the United States Patent and Trademark Office